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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,945	07/03/2003	Fangcheng Gong	CL001155CIPDIV	4691

25748 7590 02/14/2006

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EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,945	GONG ET AL.	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37, and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jo Ann Rinaudo, Group Art Unit 1644, Technology Center 1600.

2. Claims 1-3 and 24-38 are pending.

3. Applicant's election with traverse of Group II, Claim 3, (now Claims 3 and 24-36) in the reply filed on 22 December 2005 is acknowledged. The traversal is on the grounds that the search and examination necessary to examine the antibody of Group II inherently includes a search of the amino acid sequence of the polypeptides claimed in Group I, and therefore would not unduly burden the Examiner. This is not found persuasive because the polypeptide of Group I is distinct from the antibody of Group II. The polypeptides (Group I) and antibodies (Group II) are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Group III, a pharmaceutical composition comprising an agent that binds to a peptide, is distinct from Groups I (polypeptides) and II (antibodies). The pharmaceutical composition of Group III is patentably distinct from Groups I and II because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Further, a prior art search also requires a literature search. It is an undue burden on the Examiner to search more than one invention.

4. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 1, 2, 37 and 38 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to a nonelected invention.

6. Claims 3, and 24-36 are under consideration in the instant application as they are drawn to an isolated antibody that selectively binds to a polypeptide of SEQ ID NO:2.

7. The U.S. Patent No. 6,677,144, listed on Form 892, was issued from the parent applications with US serial numbers 09/901,151 and 09/799,344.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 3, 24, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Miernyk et al.

10. Miernyk et al. teaches a polyclonal antibody to a 14 amino acid fragment of pyruvate dehydrogenase (see abstract; page 9141, column 2, Results and Discussion; and page 9142, Fig.1, in particular). Further, the 14 amino acid fragment of pyruvate dehydrogenase is the same as amino acids 296-310 of SEQ ID NO: 2 in the instant application. Miernyk et al. further teach the use of the antibody as a probe of the phosphorylation sites of pyruvate dehydrogenase (see abstract and page 9143, column 1, paragraph 3, in particular). In addition, the antibody is purified from a column using a buffer (see page 9141, Immunochemical Methods, in particular). Therefore the antibody, taught by Miernyk et al., would bind to SEQ ID NO:2, of the instant application.

11. Claims 31 and 32 are included because the buffer solution associated with the antibody is considered a form of a pharmaceutically acceptable carrier.

12. Therefore the reference art teaching anticipates the claimed inventions.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 3, 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miernyk et al., in view of Harlow et al. (I).

16. Miernyk et al. has been discussed supra.

17. The claimed invention differs only by the recitation of the antibody is a monoclonal antibody (Claims 25 and 26) and the antibody is coupled to a detectable substance (Claims 27-30).

18. Harlow et al. (I) teach that monoclonal antibodies can be made by fusing B cells from an animal immunized with an antigen with myeloma cells, the fused cells are selected and grow out to secrete the antibody of desired specificity (see page 142, and pages 148-149, in particular). Further, Harlow et al. (I) teach that monoclonal antibodies are useful for their specificity of binding, homogeneity, ability to be produced in unlimited quantities, and as diagnostic reagents (see page 141, monoclonal antibodies are powerful immunological tools; and page 142, Table 6.1, in particular).

19. Harlow et al. (I) teach that antibodies can be readily labeled by covalent coupling to enzymes and a large number of enzymes have been used to label antibodies, such as alkaline phosphatase and β-galactosidase (see pages 349-352, in particular). Further, Harlow et al. (I) teach that these labeled antibodies can be used for diagnostic techniques, such as immunoblotting or immunohistochemical techniques (see page 342, in particular).

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to take the antibody that selectively binds to SEQ ID NO:2, as taught by Miernyk et al., and make monoclonal antibodies and label the antibodies, as taught by Harlow et al. (I). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Harlow et al. (I) teach that monoclonal antibodies are useful for their specificity of binding, homogeneity, ability to be produced in unlimited quantities, and as diagnostic reagents and that labeled antibodies are useful as diagnostic reagents.

21. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

22. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miernyk et al., in view of Harlow et al. (II).

23. Miernyk et al. has been discussed supra.

24. The claimed invention differs only by the recitation of a composition comprising the antibody and a pharmaceutically acceptable carrier.

25. Harlow et al. (II) teach that antibodies in compositions comprising phosphate buffered saline (PBS) can be used for immunochemical techniques (see pages 392-393, in particular).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antibody, as taught by Miernyk et al. with a pharmaceutically acceptable carrier, as taught by Harlow et al. (II). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Harlow et al. (II) teach that antibodies in compositions comprising phosphate buffered saline are used for immunochemical techniques.

27. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

28. Claims 33 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Miernyk et al., in view of Harlow (I) et al. as applied to claims 3, 24-26 above, and further in view of Harlow et al. (II).

29. Miernyk et al. and Harlow et al. (I) have been discussed supra.

30. The claimed invention further differs from the combined teachings of Miernyk et al. and Harlow et al. (I) by the recitation of a pharmaceutically acceptable carrier.

31. Harlow et al. (II) has been discussed supra.

32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the monoclonal antibody, taught by Miernyk et al. and Harlow et al. (I), with a pharmaceutically acceptable carrier, as taught by Harlow et al. (II). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Harlow et al. (II) teach that antibodies in compositions comprising phosphate buffered saline are used for immunochemical techniques.

33. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

34. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miernyk et al., in view of Harlow et al. (III).

35. Miernyk et al. has been discussed supra.

36. The claimed invention differs from the reference teachings only by the recitation of antibody fragments.

37. Harlow et al. (III) teach that antibodies can be cleaved into Fab and $F(ab')_2$ fragments (see pages 628-631, in particular). In addition, Harlow et al. (III) teach that intact antibody can cause problems in some immunochemical techniques because many cells have receptors for binding to the Fc portions of antibodies (see page 626, in particular). These problems are overcome by using antibody fragments in immunochemical techniques.

38. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to take the antibody that selectively binds to SEQ ID NO:2, as taught by Miernyk et al., and produce antibody fragments, as taught by Harlow et al. (III). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Harlow et al. (III) teach that problems using intact antibodies in immunochemical techniques can be overcome by using fragments of antibodies.

39. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

40. No claim is allowed.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

42. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.
Patent Examiner
01/26/2006

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